

State Drug Supervision and Administration Bureau

Production Approval Document

for New Drug

2000Z109

Name of New Drug	Proper Name: Zhengshengping Pian English Name: Chinese Pronunciation: Zhengshengping Pian				
Classification	Traditional Chinese Drug 3	Drug Form	Tablets	Standard	0.3g/tablet
Approval Number of Document for Test Production	(97)WeiyashiziZ-03		Approval Date		Mar 24, 1997
			Duration of Test Production		2 years
Applicant	Tianjin Central Pharmaceutical Co, Ltd.(1 Fujin Street, Beichen, Tianjin)				
Date of Application	Apr 27, 1999				
Application Decision Conclusion	Agreed approval of this product for official production				
Approval Number	Guoyaozhunzi Z20000095				
Attachment	Zhengshengping Pian quality assurance standard and Usage Information				
Principal Department to Receive this Document	Tianjin Drug Supervision and Administration Bureau				
Departments to Receive Copy of this Document	Drug Supervision and Administration Bureaus or Public Health Department (Bureau) and Drug Testing Institutes of Provinces, Autonomous Areas and Cities. Chinese People's Liberation Army General Logistic Department; Health Bureau and Drug Testing Institute. Editing Committee of Chinese Pharmacopoeia; Chinese Biological Products Testing Institute; Drug Evaluation Center of State Drug Supervision and Administration; Tianjin Central Pharmaceutical Co. Ltd.				
Remarks					

Drug Registration Department
 Of State Drug Supervision and Administration
 (with seal)
 March 25, 2000

国家药品监督管理局

新药转正式生产批件

20002109

新药名称	正式品名: 增生平片 英文名: 汉语拼音: Zengshengping Pian				
类别	中药第三类	剂型	片剂	规格	片芯重 0.3g
临床试验 批准文号	(97) 卫药试字 Z-03 号			批准日期	1997年3月24日
				试产期	二年
申请生产单位	天津市中央药业有限公司 (天津市北辰区富锦道1号)				
申请日期	1999年4月27日				
审批结论	同意本品转正式生产。				
正式生产, 批准文号	国药准字 Z20000095				
附件	增生平片质量标准及使用说明书				
主送单位	天津市药品监督管理局				
抄送单位	各省、自治区、直辖市药品监督管理局或卫生厅(局)及药品检验所, 中国人民解放军总后勤部卫生部及药品检验所, 国家药典委员会, 中国药品生物制品检定所, 国家药品监督管理局药品审评中心, 天津市中央药业有限公司				
备注					

